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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,186	07/09/2001	George Perry	PNC- 003	6017

7590 01/17/2003  
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EXAMINER

NICHOLS, CHRISTOPHER J

ART UNIT PAPER NUMBER

1647

DATE MAILED: 01/17/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicant N .

09/901,186

Applicant(s)

PERRY ET AL.

Examiner

Christopher Nichols, Ph.D.

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 7-9 and 13-17 is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1-6 and 10-12 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group I Claims 1-6 and 10-12 drawn to a method of detecting or measuring the amount of oxidative stress or damage in a subject having Alzheimer's disease in Paper No. 12 (20 November 2002) is acknowledged. Claims 7-9 and 13-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected material, there being no allowable generic or linking claim. Claims 1-6 and 10-12 will be examined to the extent that they read on a method detecting or measuring the amount of oxidative stress or damage in a subject having Alzheimer's disease. The restriction/election requirement is still deemed proper and is therefore made FINAL.

### ***Status of Application, Amendments, and/or Claims***

2. Claims 7-9 and 13-17 are withdrawn from consideration as discussed above and claims 1-6 and 10-12 are under examination.
3. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all correspondence regarding this application should be directed to Art Unit 1647, Examiner Christopher Nichols.

### ***Priority***

4. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. The effective filing date for the instant application (09/901186) is 10 July 2000 based on the provisional application 60/217087. Applicant's claim for domestic priority under 35

U.S.C. 119(e) is acknowledged. However, the provisional application (60/216648) upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-6 and 1-12 of this application. The provisional application (60/216648) does not disclose the species listed in claims 5 and 6 nor does it disclose the use of a olfactory neuron biopsy based diagnostic method for Alzheimer's disease as claimed in claims 1-4 and 10-12.

### *Specification*

6. The Specification is objected to because of the following informalities: The serial number of the provisional application to which domestic priority is claimed must appear in the first sentence of the specification (pp. 1). Appropriate correction is required.

7. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested:

METHOD OF EXAMING OLFACTORY NEURON  
SAMPLES FOR OXIDATIVE STRESS OR DAMAGE

### *Claim Objections*

8. Claims 1-6 and 10-12 are objected to because of the following informalities: claims 1-6 and 10-12 recite non-elected material. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1647

9. Claims 1-6 and 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear from the claims as to what condition, level, prevalence, or occurrence the oxidative stress markers must be in as to be diagnostic of Alzheimer's disease. Thus the claims are incomplete.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-6 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5869266 (Wolozin et al. 9 February 1999). US 5869266 teaches a method of using olfactory neuron biopsies to measure APP as a method to diagnosis Alzheimer's disease in humans. US 5869266 teaches a method of diagnosing Alzheimer's disease wherein human olfactory neurons are isolated and the tissue is cultured in vitro thus meeting the limitations of claims 1-4 and 10-12 (Col. 2 lines 22-34). US 5869266 teaches the detection of amyloid precursor protein in the olfactory neurons thus meeting the limitations of claims 5-6 and 10 (Col. 4 lines 19-24). US 5869266 also teaches the isolation of olfactory neurons from healthy and individuals with Alzheimer's disease thus meeting the limitations of claims 1 and 10 (Col. 5 lines 17-24). US 5869266 teaches a method of detecting APP as a means of diagnosing Alzheimer's disease using

anti-APP antibodies to stain olfactory neurons thus meeting the limitations of claims 2,3,5,6, and 10-12 (Col. 8 lines 29-67).

12. It is of note that claims 5 and 6 list amyloid precursor protein (APP) as an "oxidative stress marker". Therefore, APP reads on "oxidative stress marker" in claims 10, 11, and 12.

### *Summary*

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The term "subject" is read in the broadest reasonable sense, therefore it covers both living and dead human subjects. Further, Talamo et al. (Pathological Changes in Olfactory neurons in patients with Alzheimer's disease. (23 February 1989) Nature 337(23): 736-739) teaches the method of olfactory neuron biopsy to obtain neuronal tissue for Alzheimer's disease diagnostic tests on living AD patients and controls.

14. Claims 1-6 and 10-12 are hereby rejected.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher J. Nichols whose telephone number is 703-305-3955.

The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN  
January 13<sup>th</sup>, 2002

*Elizabeth C. Kemmerer*

ELIZABETH KEMMERER  
PRIMARY EXAMINER